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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,687	02/11/2002	Feng-Jing Chen	6200-0004.20	9747

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/074,687	CHEN ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,31-99 and 101-233* is/are pending in the application.

4a) Of the above claim(s) *3,4,18-23,38,67-71,88-93,108 and 134-145* is/are withdrawn from consideration.

5)☒ Claim(s) *146-233* is/are allowed.

6)☒ Claim(s) *1,2,5-17,24-29,31-37,39-49,51-66,72-87,94-99,101-107,109-116 and 118-133* is/are rejected.

7)☒ Claim(s) *50 and 117* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response dated 6-5-06 is acknowledged.

Claims1-29, 31-99 and 101-233 are pending in the instant application.

Claims 1, 2, 5-17, 24-29, 31-37, 39-66, 72-87, 94-99, 101-107, 109-133 and 146-233 have been examined. Claims 3, 4, 18-23, 38, 67-71, 88-93, 108 and 134-145 are withdrawn from consideration as being non-elected.

In response to applicants' argument, the rejection of the previous action has been withdrawn and the following rejection has been applied:

Response to Arguments

Applicant's arguments filed 11-22-06 have been fully considered and not persuasive. However, upon careful consideration the claims that have been previously indicated to be allowable have been withdrawn in view of the new rejection. Examiner regrets any inconvenience in this regard. However, examiner also indicated claims that are allowable in the last section of this action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-17, 24-29, 31-36, 37, 39-49, 51-66, 72-87, 94-99, 101-107, 109-116, and 118-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,897,269 to Mezei et al (Mezei) in view of US 6,447,806 to Gassmann et al (Gassmann).

Mezei discloses a pharmaceutical product in which a biologically active agent is present in a multiphase system i.e., A) captured in a multilamellar lipid vesicle, B) dissolved in the solvent component and C) in a solid crystalline or amorphous state (col. 4, lines 5-20), the product being dispersed in a hydrocolloid gel. Thus, the components B and C of Mezei read on the instant second and first fractions of the active agents, respectively. Examples listed in col. 7-16 (examples 1-11), include solvents such as ethanol, polyethylene glycol, which meet the requirement of the claimed solubilizers (claims 1, 43-46 and 113). With respect to the claimed percentages of the active agent (claims 5-7 and 75-77), the amount of the active agents in the examples above falls within the claimed percentages. Instant claims do not exclude liposomal formulations of Mezei. The solid particles of Mezei read on the limitations of claims 8, 9, 29, 78, 79 and 99 and the product meet the limitations of claims 1, 72 and 74.

For claims 10 and 80, Mezei discloses that the solid state of the active agent is encapsulated within the lipid vesicles. Instant claims recite that the solid particle is with a capsule but fails to state what the nature of the capsule.

For claims 24-28 and 94-98, Mezei teaches excipients such as methylcellulose (examples), which is recited in claims 28 and 98.

The composition of Mezei does not contain any water indispersible waxes and hence meet the limitations of claims 36, 37, 106 and 107. Further, the composition of Mezei does not contain water (see examples 1-9) and hence meet the claims 39, 40, 109 and 110.

With respect to the active agents of claims 47 and 114, Mezei teaches anti-fungal agent, econazole (example 6).

For claims 59, 60, 126 and 127, the composition of Mezei comprises a pharmaceutically active agent, which inherently possesses a release profile and further due to the presence of the active agent in a solid as well as a solution form, the release of the active agent in different states occurs at different rates.

Mezei does not teach the specific drugs (claims 49, 51-53, 55, 57, 115-116, 118-120, 122, 124), release properties (61-66 & 128-133), process of preparing solid particles (claims 11-17 & 81-87), claimed in the instant application. However, Mezei teaches that the different forms of active agent (solid and solution) have different rates of absorption, distribution and metabolism and therefore, absent evidence to the contrary, one of the forms of the active agent of Mezei is released earlier than the other (immediate and delayed) (col. 5, L 10-20 & col. 7, L 7-13). With respect to preparing the solid particles, Mezei suggests particles of active in the same size range as claimed (col. 12, L 25-30). Accordingly, in the absence of any unexpected advantage with the claimed method of preparing solid particles, one of an ordinary skill in the art at the time of the instant invention would have readily obtained active agent particles in the claimed range because Mezei suggests that the preparation of the multicomponent system with solid particles of claimed sizes. Mezei also suggests incorporating a number of hydrophobic drugs, (col. 6, lines 4-27), more particularly estradiol, progesterone etc (col. 9, last 4 lines) and accordingly choosing an appropriate drug in the preparation of the product of Mezei with an expectation to achieve a release preparation with different

release, absorption or metabolic rates due to different forms of active agent (solid and solution) would have been obviuous for of an ordinary skill in the art at the time of the instant invention was made. Mezei fails to teach the claimed surfactants in the composition.

While Mezei does not specifically state stabilizers in the particle fraction of the active agent, Mezei teaches polyethylene glycol, which reads on the instant solubilizers.

Alternatively, Gassmann teaches drug compositions comprising stabilized particles of active agents that are insoluble in water. Gassmann teaches stabilizing the active agent in terms of steric stabilization so as to prevent flocculation of the particles of the active agent (col. 1, L 35-45), and the second based on the charging of the particles (positive or negative) so as to stabilize the particles by their zeta-potential (col. 1). Gassmann suggests stabilizers such as glyceryl esters (col. 2), gelatin, citric acid, mannitol (col. 3), phospholipids (col. 4). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include a stabilizer in the composition of Mezei, together with the active agent that is in the dispersed because Gassmann suggests that the bioactive agents that are dispersed as amorphous particles are prone flocculation and aggregation, thus hindering their efficacy and that stabilizing the particles by adding stabilizing compounds reduces the above problems. Accordingly, a skilled artisan would have expected to reduce the aggregation of the active agents of Mezei in the presence of the stabilizers of Gassmann and thus have proper dispersion in the composition.

Allowable Subject Matter

Claims 146-233 are allowed. Claims 50 and 117 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record teaches pharmaceutical composition with an active agent in the form of solid particles as well a soluble fraction in the same product. While the art of record suggests different classes of hydrophobic drugs in general, to be incorporated in the dosage form, the prior art of record does not the specific lipid-regulating agent fenofibrate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1615
February 20, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER